

REMARKS

This response is made to the Office Action mailed December 11, 2009. Claims 1-47 are currently pending in this application. Claims 11-22 and 25-34 are withdrawn due to restriction requirement. Claim 7 has been amended and finds support at, for example, page 7, line 20 of the specification. Claims 35-47 have been added and find support in the specification and claims as originally filed. The specification has been amended to capitalize the term "EUDRAGIT" and to include its generic terminology. No new matter has been added. A Request for Extension of Time is being filed herewith.

35 U.S.C. § 112 Claim Rejections

Claim 7 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Action states that the phrase "such as" renders the claim indefinite. Although Applicants do not necessarily agree with this rejection, claim 7 has been amended in a manner Applicants believe renders this rejection moot. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112.

35 U.S.C. § 103 Claim Rejections

Claims 1-10, 23, and 24 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Publication No. 2003/0068376 (hereafter "Chen") in view of U.S. Patent No. 6,197,331 (hereafter "Lerner"). Claim 8 has been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Chen in view of Lerner, and further in view of U.S. Publication No. 2004/0037879 (hereafter "Adusumilli"). Applicants respectfully traverse these rejections at least because one of ordinary skill in the art would not be motivated to combine Chen with Lerner.

As an initial matter, Applicants submit that Adusumilli would not preclude patentability of claim 8 in view of 35 U.S.C. § 103(c). In particular, to the extent Adusumilli qualifies as prior art to the present application, it would be under 35 U.S.C. § 102(e) (Adusumilli published on February 26, 2004, after the July 24, 2003, priority date of the present application). Records indicate that both Adusumilli and the present application were under common ownership by SmithKline Beecham Corporation at the time the subject invention was made. The assignment for the present application is at Reel 017777, Frame 0420 and the assignment for Adusumilli is at Reel 013581 Frame 0852. Accordingly, Adusumilli is not available as prior art in accordance with 35 U.S.C. § 103(c) and Applicants respectfully request withdrawal of the rejection of claim 8 under 35 U.S.C. § 103(a).

With respect to the combination of Chen with Lerner, Chen is directed to "an intraoral **quick-dissolving** film which is applied lingually. The dosage form is applied to the **tongue** . . . and rapidly

disintegrates, dissolves and releases [nicotine]." (Chen, paragraph [0051]) (emphasis added). As recognized by the Action, Chen does not teach the use of enteric polymers for its film. Rather, the films in Chen comprise a non-microbial hydrocolloid and nicotine. Chen describes this non-microbial hydrocolloid as water soluble and non-gelling natural gums or derivatives thereof, water soluble and non-gelling polypeptides, and water soluble synthetic polysaccharides. There is no suggestion in Chen that these water soluble components can or should be replaced with enteric polymers or that enteric polymers would produce the described **quick-dissolving** film. The quick-dissolving film of Chen provides for "a relatively rapid initial increase in blood nicotine concentration [that] simulate[s] the pattern obtained by smoking a cigarette or taking a nasal spray." (Chen, paragraph [0052]).

Lerner is directed to an oral patch that "**adhere[s]** to **hard dental surfaces**, such as teeth and dentures." (Lerner, col. 1, lines 11-12) (emphasis added). The oral patch is designed to remain on the tooth or denture for a period of time and provide **controlled or sustained release** of pharmaceutical agents to the patent. Although Lerner refers to certain Eudragit® polymers as suitable polymers for release layers and/or adhesive layers, there is no discussion of these polymers imparting "quick dissolving" characteristics on the oral patch.¹ This lack of teaching is consistent with the understanding of one skilled in the art with respect to enteric coatings – enteric polymers are useful for **delayed** release of an active agent until a particular dosage form reaches the intestine. Although Lerner employs certain enteric polymers for delivery of pharmaceuticals to the oral cavity, Lerner repeatedly refers to **controlled or sustained release** characteristics of the oral patch. Additionally, Lerner further distinguishes itself from quick dissolving films, like those disclosed in Chen. Lerner states that a significant advantage of its "oral patch" over films is that the oral patch provides for greater adhesion than films, resulting in treatment for longer periods of time (Lerner, col. 10, lines 17-26).

When both references are viewed in their entirety, one skilled in the art would not be motivated to combine the film of Chen with the polymers of Lerner. Whereas Chen is directed to a film comprising water-soluble polymers that is applied to the tongue and quickly dissolves to release nicotine, Lerner is directed to a patch that adheres to a tooth or denture and provides for a controlled or sustained release of a pharmaceutical agent. This is further emphasized in view of

¹ The Action refers to column 7, lines 1-4 of Lerner, but this language is directed to the speed at which the pharmaceutical is systemically delivered via buccal absorption, not the speed at which the composition is dissolved.

Serial No.: 10/565,706
Group Art Unit No.: 1611

Lerner's teachings about its benefits over "films" and the understanding of those skilled in the art with respect to the dissolution characteristics of the enteric polymers disclosed in Lerner.

With respect to claim 3, Applicants further submit that even if one were to combine Chen with Lerner, they would not arrive at the claimed invention. Neither of the references teaches an orally dissolving film composition comprising a **pre-neutralized**, enteric polymer. As recognized by the Action, Chen does not teach the use of any enteric polymers and although Lerner does mention the use of enteric polymers, it does not teach or suggest the use of **pre-neutralized** enteric polymers.

Accordingly, for at least these reasons, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an indication of allowability of all pending claims is requested respectfully. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

/Joshua C. Sanders/
Joshua C. Sanders
Attorney for Applicants
Registration No. 62,439

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270- 6857
Facsimile (610) 270-5090